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News

West Virginia Board of Pharmacy

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Beware of Illegal Internet Pharmacy Schemes

The governor's substance abuse legislation, SB 437, became effective June 8, 2012. Included in the legislation is a clarification of the law in WV Code §30-5-3(g). This subsection was designed to curb illegal prescriptions for Internet pharmacy without a legitimate doctor-patient relationship, and the new clarification further nails this down given the expansion of such operations across the country. That section, as amended, states in relevant part:

> No pharmacist may compound or dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing a **valid practitioner-patient relationship. An online or telephonic evaluation by questionnaire, or an online or telephonic consultation, is inadequate to establish a valid practitioner-patient relationship.**

This provision, of course, is subject to some exceptions for cross-coverage and the like. The language about online or telephonic evaluations by **questionnaire** has existed in the code for many years, and the modification this year was simply to add the language about online or telephonic **consultations.** This is a minor, but needed, clarification to guard against potential arguments trying to get around the requirement. In short, a prescriber has to have a valid relationship with the patient, which is going to require some face-to-face interaction and examination to establish it in the first place. If the patient is in one state, and the prescriber in another, that should be a red flag for a pharmacist to inquire as to whether a proper practitioner-patient relationship exists.

The West Virginia Board of Pharmacy has recently worked with a couple of situations where illegal Internet operations were working in West Virginia. The situations were resolved amicably with the West Virginia pharmacies and personnel, without discipline by the Board, based upon them voluntarily ceasing the practice. If you are involved in a situation like this, please report it to the Board and stop immediately. If the Board otherwise learns of more situations like this, future substantiated cases will likely result in discipline.

Expansion of Pharmacist Immunizations

The Board of Pharmacy went through joint rulemaking with the Board of Medicine and Board of Osteopathy to amend Rule 15-12-2.2 to allow for four more vaccines that pharmacists can administer. You can now administer flu; pneumonia; Hepatitis A; Hepatitis B; Herpes Zoster; and Tetanus, Tetanus-Diphtheria, and Tetanus-Diphtheria-Pertussis vaccines. You do not have to have a prescription; you can follow the Centers for Disease Control and Prevention protocols. Of course, if you receive a prescription, you can follow it if you believe it is an appropriate prescription. The only other change is to require by rule for reporting any adverse events to the federally created and maintained Vaccine Adverse Event Reporting System (VAERS), with a copy sent to the Board of Pharmacy (§15-12-6.4). See *http://vaers.hhs.gov/index* for reporting to VAERS. This will help the Board deal with any adverse events on a state level, and provide data to the Boards of Medicine and Osteopathy about the programs offered through pharmacists.

Daily Reporting to CSMP; Counseling Offer Required on Pseudoephedrine Sales

The governor's substance abuse bill, SB 437, became effective June 8, 2012. Among other things, it made changes to the West Virginia Controlled Substances Monitoring Program (CSMP), and to the Methamphetamine Laboratory Eradication Act. These new provisions place added requirements on pharmacies and their staffs.

- *Daily Reporting to the CSMP:* Regarding the CSMP, among many other things, the new law states that the Board may require reporting of all dispensings of Schedule II-IV controlled substance prescriptions to the CSMP within 24 hours. As such, the Board prepared emergency rules that modified Series 8 of the rules, to require that dispensers report their dispensings of controlled substances to the

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CSMP within 24 hours of the dispensing (48 hours if done by mail). It also requires filing "zero" reports if you do not have any dispensings within 24 hours of the prior reporting, and do not have a waiver from reporting (such waiver is available to those dispensers who do not stock any Schedule II-IV controlled substances).

- *Counseling Offer Required for Over-the-Counter PSE Sales:* The new law also changes several things with sale of methamphetamine-precursors – pseudoephedrine or ephedrine containing products (PSE). In addition to moving to the national real-time point-of-sale database commonly referred to as National Precursor Log Exchange or MethCheck by January 1, 2013, the new law limits the amount of grams a person may purchase in any 30-day period to 7.2 grams, and to no more than 48 grams in any one-year period. Also, effective June 8, 2012, on every sale of PSE products from behind the counter, an offer to counsel the purchaser must be given. Pharmacies will need to modify their processes accordingly.

E-Signatures for Non-Controlled Prescriptions Now Acceptable

Electronic prescribing of controlled substances (EPCS) is permitted by the rules promulgated by the Board. However, it is subject to compliance with federal Drug Enforcement Administration (DEA) rules on EPCS, including having the prescriber's and the dispenser's EPCS systems both certified as appropriate systems under DEA law. Until then, many prescriber's prescriptions for controlled and non-controlled substances are being converted from electronic prescriptions by either the prescriber's system, their third-party data intermediary, or the pharmacy's system. In the case of controlled substances, DEA law is clear that a wet signature by the prescriber is required on any written prescription, including faxed or e-faxed prescriptions. However, for non-controlled prescriptions, prescribers requested the Board to consider the electronic or digitized signatures on prescriptions that are faxed or e-faxed to the pharmacy be considered as legally signed prescriptions by the Board. The Board reviewed the issue at its March meeting, and passed a motion to accept e-signatures on non-controlled prescriptions that are faxed or e-faxed to the pharmacy. During discussion of the motion it was explained that this would include "digitized" signatures (a computer-generated copy of the prescriber's written signature stored in his or her prescribing system), and that, just as with oral prescriptions, the pharmacy must have sufficient assurance that the faxed prescription did come from the prescriber and is otherwise a legal prescription.

Animal Drug Product Added as Approved Generic Substitute

West Virginia is an *Orange Book* state for generic substitution. However, the *Orange Book* pertains only to human drugs. As such, representatives of FidoPharm® presented their request to the Board to separately recognize their animal drug product, PetTrust Plus® Chewable Tablets, as an acceptable generic substitute for Tri-Heart Plus® and Heartgard Plus® Chewable Tablets. Based upon the review of the Food and Drug Administration Abbreviated New Animal Drug Application (ANADA) and ANADA process and other materials submitted in support of their request the Board passed a motion to approve the request and add PetTrust Plus Chewable Tablets as a proper generic substitute for Tri-Heart Plus and Heartgard Plus Chewable Tablets under West Virginia law.

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West Virginia Board of Pharmacy

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